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EXAMINER	
CUMBERLEDGE, JERRY L	

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3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/795,887	BONUTTI, PETER M.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177).

Waugh et al. disclose a method of performing surgery on a patient's knee, the method comprising: suspending a distal portion of a patient's leg from the knee (column 4, lines 46-50); positioning a guide member against the bone (column 5, lines 21-26); cutting a bone of the knee with a cutting tool while the distal portion of the patient's leg is suspended from the knee (column 4, lines 58-63), said step of cutting includes initiating a cut in the bone while guiding the cutting tool along a guide surface of the guide member to form a cut surface (column 5, lines 21-26), then completing a skim cut (i.e. an anterior femoral cut, as seen in Fig. 2) , while guiding the cutting tool along the cut surface, since the anterior femoral cut must have been made using a guide, as it is such a uniform cut (Fig. 2) (column 5, lines 21-26); and positioning a total knee replacement component against the cut bone of the knee (column 6, lines 11-14 and column 6, lines 28-31), wherein cutting the bone includes cutting first and second condyles of the bone (column 4, lines 59-64), wherein the length of the completed cut is at least as long as the distance between the first and second condlyles, since the cut is

shown extending across the entire end portion of the bone (Fig. 2). Positioning the total knee replacement component includes positioning a first portion of the total knee replacement against the cut bone, and subsequently positioning a second portion of the total knee replacement component against the cut bone (column 6, lines 11-14 and column 6, lines 28-31). The method further includes the step of connecting the first and second portions of the total knee replacement component after both portions have been positioned against the cut bone (Fig. 2). Suspending the distal portion of the patient's leg from the knee includes bending the knee to a flexed condition (column 4, lines 48-50), and cutting the bone of the knee includes cutting the bone of the knee while the knee is bent in the flexed condition (column 4, lines 58-64). Bending the knee includes hyperflexing the knee (Fig. 1)(column 4, lines 58-64), and cutting the bone of the knee includes cutting the bone of the knee while the knee is hyperflexed (column 4, lines 58-64).

Waugh discloses the claimed invention except for the step of removing the guide member from against the bone and then completing a skim cut, wherein the skim cut has a dimension in a direction parallel to a central axis of the guide surface which is greater than the distance between opposite ends of the guide member.

Whiteside discloses a surgical method for the knee (abstract) that comprises using a guide, removing the guide and finishing a cut of the condyles of a knee (column 9, lines 62-64), since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have

dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Waugh et al. with a step of using a guide, removing a guide and finishing a cut of the condyles of a knee as taught by Whiteside, since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177) in view of Sherwin (US Pat. 3,750,652).

Waugh et al. in view of Whiteside disclose the claimed method except for the method further includes distracting the knee while the distal portion of the patient's leg is suspended from the knee, and wherein at least one of the steps of cutting the bone and positioning the total knee replacement component is performed while the knee is distracted.

Sherwin discloses distracting the knee (column 1, lines 58-67) during a surgical procedure (column 1, lines 1-10), in order to allow increased visibility to the area that the surgery is being performed on (column 1, lines 40-41 and column 1, lines 58- 67).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have added the step of distracting the knee during a surgical

procedure as taught by Sherwin to the method of Waugh et al. in view of Whiteside, in order to allow increased visibility to the area that the surgery is being performed on (column 1, lines 40-41 and column 1, lines 58- 67).

Claims 9, 10, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177) in view of Shapiro (US Pat. 4,565,192).

Waugh et al. in view of Whiteside disclose the claimed method except for the method further includes displacing a patella of the knee. The method further includes cutting the patella while the patella is displaced. The patella is displaced with an inner side of the patella remaining facing inward. The method further includes everting a patella of the knee. The method further includes cutting the patella while the patella is everted.

Shapiro discloses displacing a patella of the knee (column 10, lines 21-26). The method further includes cutting the patella while the patella is displaced (column 10, lines 29-36). The patella is displaced with an inner side of the patella remaining facing inward, since, as the patella is first being displaced, it will still be facing inward as it normally is (column 10, lines 21-26). The method further includes everting a patella of the knee (column 10, lines 21-26). The method further includes cutting the patella while the patella is everted (column 10, lines 29-36). These steps allow for the implantation of a prosthesis in order to restore the diseased patella to normal functioning (column 2, lines 64-67 and column 3, lines 1-2).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have added the steps of displacing a patella and cutting a patella as taught by Shapiro to the method of Waugh et al. in view of Whiteside, in order to allow for the implantation of a prosthesis in order to restore the diseased patella to normal functioning (column 2, lines 64-67 and column 3, lines 1-2).

Claims 9, 10, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177) in view of Waddell (US Pat. 6,174,314).

Waugh et al. in view of Whiteside disclose the claimed method except for the method further includes displacing a patella of the knee. The method further includes cutting the patella while the patella is displaced. The patella is displaced with an inner side of the patella remaining facing inward. The inner side of the patella remains facing inward during the cutting and positioning steps.

Waddell discloses displacing a patella of the knee, since as the knee is moved (column 3, lines 22-24) the patella will be displaced. The method further includes cutting the patella while the patella is displaced (column 3, lines 29-32). The patella is displaced with an inner side of the patella remaining facing inward (column 8, lines 14-15). The inner side of the patella remains facing inward during the cutting and positioning steps (column 8, lines 14-15). Not everting the patella during the procedure decreases the failure of total knee arthroplasty (column 2, lines 63-67 and column 3, lines 1-8).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have added modified the method of Waugh et al. in view of Whiteside with the step of displacing the patella and not everting the patella, in order to decrease the failure of total knee arthroplasty (column 2, lines 63-67 and column 3, lines 1-8).

Claims 15-18 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Techiera (US Pat. 6,106,529 in view of Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177).

Techiera discloses a method of performing surgery on a patient's joint, the method comprising: positioning a guide member against a bone of the joint (column 3, lines 48-54), the guide member having a guide surface (Fig. 1); positioning a cutting tool in association with the guide surface of the guide member (column 3, lines 8-10)(column 5, lines 45-54); initiating a cut in the bone while guiding the cutting tool along the guide surface to form a cut surface (column 3, lines 8-10)(column 5, lines 45-54); continuing the cut in the bone while guiding the cutting tool along the cut surface (column 3, lines 8-10) (column 5, lines 45-54). The method further includes positioning an implant against the cut bone (column 53-56). Positioning the implant includes positioning first and second portions of the implant against the cut bone (column 3, lines 37-41, *i.e.* components are postioned). Positioning first and second portions of the implant includes connecting the first and second portions of the implant (column 1, lines 33-38). Initiating the cut and completing the cut are performed on a condyle of the bone (column 1, line

67 and column 2, lines 1-6), and further including positioning a partial joint replacement component against the cut condyle of the bone (column 53-56). Initiating the cut and completing the cut are performed on both condyles of the bone (column 1, lines 50-67 and column 2, lines 1-6)(column 5, lines 24-30), and further including positioning a total joint replacement component against the cut condyles of the bone (column 1, lines 25-30). The method further includes completing the cut while guiding the cutting tool along the cut surface (column 2, lines 61-65). The method further includes removing the guide member from the bone before continuing the cut (column 6, lines 46-50). The guide surface comprises a guide slot and the step of positioning a cutting tool includes inserting the cutting tool into the guide slot (column 5, lines 45-54).

Techiera does not disclose the step of positioning a first portion of a total knee replacement component against the cut bone, and subsequently positioning a second portion of the total knee replacement component against the cut bone; and connecting the first and second portions of the total knee replacement component after both portions have been positioned against the cut bone, each of the first and second portions of the total knee replacement component having an articulating surface. Waugh et al. discloses a step of knee surgery (abstract) comprising a step of positioning a first portion of a total knee replacement component against the cut bone (column 6, lines 11-27), and subsequently positioning a second portion of the total knee replacement component against the cut bone (column 6, lines 28-28-31); and connecting the first and second portions of the total knee replacement component after both portions have been positioned against the cut bone (column 6, lines 43-49), each

of the first and second portions of the total knee replacement component having an articulating surface (Fig. 2). This type of two-part prosthesis is useful in that it allows for flexion, rotation, rolling and sliding movements substantially reproducing those movements of the normal human knee (column 2, lines 16-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Techiera with the prosthesis of Waugh et al. and its associated method steps in order to provide a total knee replacement that allows for flexion, rotation, rolling and sliding movements substantially reproducing those movements of the normal human knee (column 2, lines 16-24).

Techiera in view of Waugh et al. disclose the claimed invention except for the step of removing the guide member from against the bone and then completing a skim cut, wherein the skim cut has a dimension in a direction parallel to a central axis of the guide surface which is greater than the distance between opposite ends of the guide member.

Whiteside discloses a surgical method for the knee (abstract) that comprises using a guide, removing the guide and finishing a cut of the condyles of a knee (column 9, lines 62-64), since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Techiera in view of Waugh et al.

with a step of using a guide, removing a guide and finishing a cut of the condyles of a knee as taught by Whiteside, since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Techiera in view of Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177).

Techiera discloses the claimed method except for suspending a distal portion of a patient's extremity connected with the joint, and initiating the cut and completing the cut are performed while the distal portion of the patient's extremity connected with the joint is suspended.

Waugh et al. disclose suspending a distal portion of a patient's extremity connected with the joint (column 4, lines 46-50), and initiating the cut and completing the cut are performed while the distal portion of the patient's extremity connected with the joint is suspended (column 4, lines 58-63). This, in part, provides excellent exposure to the anterior aspect of the entire knee joint (column 4, lines 52-53).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Techiera with the step of suspending a portion of the extremity and cutting the extremity while suspended as taught by Waugh et al. This step would provide better exposure to the anterior aspect of the entire knee joint.

Techiera in view of Waugh et al. disclose the claimed invention except for the step of removing the guide member from against the bone and then completing a skim cut, wherein the skim cut has a dimension in a direction parallel to a central axis of the guide surface which is greater than the distance between opposite ends of the guide member.

Whiteside discloses a surgical method for the knee (abstract) that comprises using a guide, removing the guide and finishing a cut of the condyles of a knee (column 9, lines 62-64), since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Techiera in view of Waugh et al. a step of using a guide, removing a guide and finishing a cut of the condyles of a knee as taught by Whiteside, since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Techiera (US Pat. 6,106,529) in view of Waugh et al. (US Pat. 3,869,731) in view of Whiteside (US Pat. 4,474,177) in view of Sherwin (US Pat. 3,750,652).

Techiera in view of Waugh et al. disclose the claimed method except for distraciing the joint, and wherein at least one of the steps of positioning the guide member, positioning the cutting tool, initiating the cut, and completing the cut is performed with the joint distracted.

Sherwin discloses distracting a joint (column 1, lines 58-67) during a surgical procedure (column 1, lines 1-10), in order to allow increased visibility to the area that the surgery is being performed on (column 1, lines 40-41 and column 1, lines 58- 67).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have added the step of distracting the knee during a surgical procedure as taught by Sherwin to the method of Techiera in view of Waugh et al. in view of Whiteside, in order to allow increased visibility to the area that the surgery is being performed on (column 1, lines 40-41 and column 1, lines 58- 67).

Claims 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Techiera (US Pat. 6,106,529) in view of Matsen, III et al. (US Pat. 4,979,949) in view of Whiteside (US Pat. 4,474,177).

Techiera discloses a method of performing a total knee arthroplasty surgery on a leg of a patient, the method comprising: positioning a guide member against a bone of a knee joint in the leg of the patient (column 3, lines 48-54), the guide member having opposite ends with a transverse dimension which is less than a distance between medial and lateral epicondyles of an end portion of the bone (Fig. 1); positioning a cutting tool in association with a guide surface of the guide member (column 1, line 67

and column 2, lines 1-6); initiating a cut in the bone while guiding the cutting tool along the guide surface to form a cut surface (column 1, line 67 and column 2, lines 1-6); and continuing the cut in the bone while guiding the cutting tool along the cut surface (column 1, line 67 and column 2, lines 1-6), wherein both medial and lateral condyles of the end portion of the bone are cut by the cutting tool (column 1, line 67 and column 2, lines 1-6). The method further includes positioning an implant against the cut bone (column 1, lines 18-21). The guide member is mounted to the bone (Fig. 1) and offset from a central longitudinal axis of the bone (column 2, lines 20-25). The guide member is intramedullary mounted to the bone (column 4, lines 36-41). The guide member is extramedullary mounted to the bone (column 4, lines 62-64). The guide is operative when at least half of the guide body is disposed laterally to a line defining the longitudinal axis of the bone to be cut. The guide is operative when at least one end is positioned between the skin and the bone to be cut. With regard to the guide being operative, the examiner is interpreting this as meaning the guide is capable of being operated when the guide is placed as claimed, but is not required to be operated when the guide is placed as claimed.

Techiera discloses the claimed invention except for the method including the step of angularly disposing the cutting tool along the guide surface in order to cut a section of the bone wider than the width of the guide.

Matsen, III et al, discloses a method of knee surgery (Fig. 3) in which a saw blade is angled with respect to a guide surface (column 23, lines 43-52), so that the

guide can be used near a bone end in a manner that minimally interfaces with the overall view of the bone (column 23, lines 43-52).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the method of Techiera with the step of angularly disposing the cutting tool along the guide surface, which would allow the guide to be used near a bone end in a manner that minimally interfaces with the overall view of the bone (column 23, lines 43-52).

Techiera in view of Matsen, III et al. disclose the claimed invention except for the step of removing the guide member from against the bone and then completing a skim cut, wherein the skim cut has a dimension in a direction parallel to a central axis of the guide surface which is greater than the distance between opposite ends of the guide member.

Whiteside discloses a surgical method for the knee (abstract) that comprises using a guide, removing the guide and finishing a cut of the condyles of a knee (column 9, lines 62-64), since it is sometimes necessary for a surgeon to remove a guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have created the method of Techiera in view of Matsen, III et al. with a step of using a guide, removing a guide and finishing a cut of the condyles of a knee as taught by Whiteside, since it is sometimes necessary for a surgeon to remove a

guide in order to continue cutting the condyles (column 9, lines 62-64). The cut would have dimensions longer than some of the distances between opposite ends of the cutting guide (Fig. 9).

With regard to claim 28, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the transverse dimension of the opposite ends of the guide member of Techiera in view of Waugh et al. being less than two-thirds the distance between the medial and lateral epicondyles of the end portion of the bone, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC